REMARKS

Claims 1-20 are pending in this application. Claims 1-16 and 18-20 were rejected under 35 U.S.C. §112, first paragraph. Claims 1-16 and 18-20 were rejected under 35 U.S.C. §103(a).

By this amendment, claims 1, 2, 3, 14, and 17 have been amended, and new claims 21 and 22 have been added, without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments and new claims can be found, *inter alia*, throughout the specification and the claims as originally filed. For example, support for the amendments and new claims can be found in paragraphs [0023]-[0025] at pages 6-8 of the specification. Accordingly, no new matter has been added.

The amendment is made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover, have not acquiesced to any rejections or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-16 and 18-20 were rejected under 35 U.S.C. §112, first paragraph for allegedly not enabling any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Applicants respectfully traverse this rejection.

As amended herein, the claimed invention is directed to methods for treating pancreatitis through administration of an amylin or an amylin analog with amylin agonist activity. As described in paragraph [0024] the specification, an amylin analog refers to a compound that is similar in structure to amylin and mimics an effect of amylin *in vitro* or *in vivo*.

The Examiner acknowledges that the specification is enabling for a method of treating pancreatitis and/or relieving the pain caused by pancreatitis comprising administering an effective amount of the amylin analog ^{25,28,29}Pro-h-amylin. However, the Examiner asserts that the specification does not enable the claimed methods comprising "administering any and/or all amylin analogs." Office Action, page 2. Applicants respectfully disagree with this assertion.

Amylin analogs for use in the present invention are described in the specification and well known in the art. For example, paragraphs [0025]-[0033] of the specification provide representative examples of amylin analogs for use in the claimed invention. Amylin analogs with amylin activity were also known in the art at the time the present application was filed. For example, amylin analogs for use in the invention include those described in U.S. Pat. Nos. 5,686,411, 6,114,304, and 6,410,511, submitted herewith in a supplemental Information Disclosure Statement. These patents include the amylin analog ^{25,28,29}Pro-h-amylin, amylin analogs having the formula outlined in paragraph [0025] of the specification and those in paragraphs [0032] and [0033] of the specification. These amylin analogs have been shown to mimic an effect of amylin *in vitro* or *in vivo*. For example, as shown in Examples 18 and 19 of U.S. Pat. No. 5,686,411, many of these amylin analogs possess amylin activity (receptor binding or muscle assay) comparable to that of human amylin and to that of ^{25,28,29}Pro-h-amylin.

In addition, conventional assays for identifying amylin analogs and for detecting amylin activity of compounds are described in the specification and known in the art. For example, paragraphs [0034]-[0044] and [0089]-[0099] of the specification describe how to make amylin analogs and how to assess the compounds for amylin activity. U.S. Pat. Nos. 5,686,411, 6,114,304, and 6,410,511 also provide such information.

The Examiner states that the art, at the time the application was filed, "did not recognize a method for treating pancreatitis and/or relieving the pain caused by pancreatitis comprising administering any and/or all amylin analogs" and asserts that the specification fails to provide guidance or working examples for the claimed methods comprising administering any and/or all amylin analogs.

Applicants respectfully note that the test for enablement is not whether a certain amount of experimentation is required to practice an invention, but rather whether the amount of experimentation is "undue." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). "Since one embodiment is ... disclosed in the specification, along with the general manner in which its current range was ascertained, ... other permutaions of the invention could be practiced by those skilled in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d. 788, 8 USPQ2d 1217 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). Applicants respectfully submit that the specification provides a reasonable amount of guidance to the skilled artisan and that any additional necessary experimentation is presumed to be within the level of ordinary skill in the art.

The specification, including the examples, illustrates the operation of the invention. Amylin analogs and assays for identifying amylin analogs with amylin agonist activity are described in the specification and known in the art. Following these teachings, using amylin analogs other than ^{25,28,29}Pro-h-amylin is not seen to involve undue experimentation. Thus, Applicants respectfully submit that the specification adequately teaches the skilled artisan how to make and use, *i.e.*, enables, the claimed invention.

Thus, Applicants respectfully submit that a *prima facie* case of lack of enablement has not been established and the pending claims are in compliance with the enablement requirements.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 112, first paragraph.

Rejections under 35 U.S.C. §103

Claims 1-16 and 18-20 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Young *et al.* (U.S. Pat. No. 5,677,279; hereinafter "Young") in further view Braganza *et al.* (U.S. Pat. No. 5,196,402; hereinafter "Braganza") and Jorgensen *et al.* (U.S. Pat. No. 4,370,317; hereinafter "Jorgensen"). Applicants respectfully traverse this rejection.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, the references when combined must teach or suggest all the claim limitations. Second, there must be

some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally there must be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991): MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. For reasons discussed below, the cited references do not fulfill these requirements for *prima facie* obviousness.

Claim 1 is directed to administration of an amylin or an amylin analog for treating pancreatitis. Claim 14 is directed to a method of improving a treatment for pancreatitis through administration of an amylin or an amylin analog in addition to an agent or regimen used to treat pancreatitis. The claimed invention lies in the discovery that administration of a compound with amylin activity can be used to treat pancreatitis, an inflammatory process in which pancreatitic enzymes are released into the pancreas and surrounding tissues. As described and demonstrated in the specification, administration of a compound with amylin activity reduces pancreatic enzyme secretion thereby treating pancreatitis.

Young describes the use of an amylin or amylin agonist for treating or preventing pain. Young is does not teach or suggest the use of an amylin or an amylin agonist for treating pancreatitis.

Braganza describes the use of S-adenosyl-methionine for the treatment of pancreatitis and for reducing graft rejections. Jorgensen describes the isolation of pancreatic spasmolytic polypeptide and its use in reducing intestinal motility. Neither Braganza nor Jorgensen describes treating the pain of pancreatitis. Neither Braganza nor Jorgensen mentions or suggests the use of an amylin or an amylin agonist for use in treating pancreatitis.

In support of this rejection, the Examiner states that "when the same amylin analog as the claimed invention's analog of ^{25,28,29}Pro-h-amylin in combination with an analgesic are administered to a mammalian subject for treating pain, it would intrinsically treat the painful disorder of pancreatitis within a mammalian subject when treating the pain." Office Action, pages 5-6. Applicants respectfully disagree with this basis for the obviousness rejection.

The Federal Circuit has held that the "fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); emphasis in original. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson* 169 F.3d 743, 745 (Fed. Cir. 1999); emphasis added.

Although pancreatitis can be a painful disorder, not all patients with pain necessarily have pancreatitis. Accordingly, a reference which teaches treating pain with an amylin or amylin agonist does not necessarily teach treating patients with pancreatitis as claimed. Thus, treating pancreatitis cannot be recognized by one skilled in the art as inherently taught in Young. Young does not explicitly or inherently teach treating pancreatitis as claimed.

In fact, none of the cited references, either alone or combined, teach that an amylin or an amylin analog can reduce the level of pancreatic enzyme secretion or activity. Accordingly, alone or combined, the cited references do not teach or suggest that an amylin or an amylin analog can be used to treating pancreatitis. Thus, the cited references do not support a *prima facie* case of obviousness.

Further, a *prima facie* case of obviousness also requires that there be some suggestion or motivation to modify the reference or to combine reference teachings. The fact that the references can be combined is insufficient to establish *prima facie* obviousness in the absence of a suggestion or motivation to make such a combination. Simply stated, the suggestion or motivation to combine the references must be found in the prior art. Without a motivation to combine the cited references, a rejection based on a *prima facie* case of obvious is improper. *In re Rouffet*, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Applicants respectfully submit that there is no motivation to combine or modify the teachings of Young with that of Braganza and Jorgensen to arrive at the claimed invention.

Young describes treating pain with an amylin agonist but is silent with regard to treating pancreatitis. Neither Braganza nor Jorgensen describes treating pain generally nor treating the

pain of pancreatitis specifically. Thus, the cited references provide no suggestion or motivation to combine the teachings of the references to result in the claimed method. There simply is no suggestion in Young to look to the pancreatitis art to modify the teachings therein. Likewise, neither of Braganza and Jorgensen suggests modifying their teachings with amylin or amylin agonists as taught by Young.

Finally, none of the cited references, alone or combined, teach that amylin or an amylin agonist can reduce the level of pancreatic enzyme secretion or activity. Thus, the cited references provide no expectation of success.

In sum, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and that the cited references do not render obvious the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535 referencing Docket No. 0101-UTL-0. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Date: 18 October 2006

Respectfully submitted,

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